

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

-----X
STEVEN W. SAMPSON, TRUSTEE,

Plaintiff,

-against-

JAMES D. ROBINSON III, LEWIS B. CAMPBELL,
JAMES M. CORNELIUS, LAURIE H. GLIMCHER,
M.D., VICKI L. SATO, PH.D., LEIF JOHANSSON,
LOUIS J. FREEH, MICHAEL GROBSTEIN, and
R. SANDERS WILLIAMS, M.D.,

Defendants,

and

BRISTOL-MYERS SQUIBB COMPANY,

Nominal Defendant.
-----X

07 Civ. 6890 (PAC)

**FILED
ELECTRONICALLY**

**SECOND DECLARATION OF LORIN L. REISNER
IN SUPPORT OF MOTION TO DISMISS**

Lorin L. Reisner hereby declares as follows:

1. I am a member of the bar of this Court and the law firm Debevoise & Plimpton LLP, counsel for nominal defendant Bristol-Myers Squibb Company (“BMS”).

This declaration is submitted in further support of the motion to dismiss this action.

2. Attached as Exhibit A is a true and correct copy of an Opinion and Order dated December 11, 2007, issued by Justice Herman Cahn in *Beebout v. Dolan, et al.*, Index No. 602579/07 (N.Y. Supreme Court).

3. Attached as Exhibit B are excerpts from a Form 10-Q filed by BMS with the Securities and Exchange Commission on August 8, 2006, including Exhibit 99.1 (Proposed Settlement Agreement) and Exhibit 99.2 (Modified Proposed Settlement Agreement).

I declare under penalty of perjury that the foregoing is true and correct.

/s/ Lorin L. Reisner
Lorin L. Reisner

Dated: New York, New York
January 7, 2008

EXHIBIT A

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK: PART 49

-----X
DONALD BEEBOUT, Derivatively on Behalf of
Nominal Defendant
BRISTOL-MYERS SQUIBB COMPANY,

Plaintiff,

-against-

INDEX NO. 602579/07

PETER R. DOLAN, ANDREW BODNAR,
JAMES M. CORNELIUS, JAMES D.
ROBINSON III, LEWIS B. CAMPBELL,
LOUIS J. FREEH, LAURIE H. GLIMCHER
and LIEF JOHANSSON,

Defendants,

- and -

BRISTOL-MYERS SQUIBB COMPANY,

Nominal Defendant.

-----X
HERMAN CAHN, J:

Plaintiff, David Beebout, a shareholder of nominal defendant Bristol-Myers Squibb Company ("Bristol-Myers"), brings this shareholder derivative action against several members of Bristol-Myers Board of Directors ("Moving Defendants")¹, certain former Bristol-Myers executive officers² and nominal defendant Bristol-Myers, for damages resulting from the alleged breach of their fiduciary duties. The director defendants and nominal defendant Bristol-Myers

¹ The Director Defendants are James M. Cornelius ("Cornelius"), James D. Robinson III ("Robinson"), Lewis B. Campbell ("Campbell"), Louis J. Freeh ("Freeh"), Laurie H. Glimcher ("Glimcher") and Leif Johansson ("Johansson").

² Peter R. Dolan ("Dolan"), was Bristol-Myers chief executive officer until his termination on September 12, 2006. Andrew Bodnar ("Bodnar") was a senior vice president until his termination in September, 2006.

move to dismiss the amended complaint on the ground that plaintiff failed to make a pre-suit demand on Bristol-Myers Board of directors, or sufficiently plead demand futility through particularized allegations in the complaint.³

Bristol-Myers is incorporated in Delaware. Its business is development, manufacture, distribution and sale of pharmaceuticals and other health related products. At the time this action was commenced, Bristol Myers's Board of Directors consisted of nine directors.

The complaint alleges that defendants Cornelius, Robinson, Campbell, Freeh, Glimcher and Johansson were members of both the Board and its Audit Committee and, as Audit Committee members, they met periodically with Bristol Myers's Chief Compliance Officer and General Counsel to discuss legal matters that might have a material impact on the company's financial statements and/or policies and procedures. (9/12/07 Reisner Aff, Ex. B, hereinafter "Complaint", para. 18)

Plavix, a drug that is said to prevent heart attacks and strokes, has been Bristol-Myers top selling product for the past three years. In November, 2001, Apotex, a Canadian pharmaceutical company, filed an application with the United States Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic form of Plavix. Upon learning of Apotex's plans, Bristol-Myers filed a patent infringement lawsuit against Apotex.⁴ Apotex counterclaimed alleging that Bristol-Myers's patent was invalid.

³ Although the moving defendants submitted their motion to dismiss before plaintiff amended the complaint, they now request that the court apply the motion to dismiss to the amended complaint. (*Sage Realty Corp. v. Proskauer Rose LLP*, 251 A.D.2d 35, 38 [1st Dept 1998]). That request is granted.

⁴ Bristol-Myers patent on Plavix runs until 2011.

In March, 2006, Bristol-Myers and Apotex entered into a settlement agreement to resolve the litigation. However, in accordance with a pre-existing consent order with the Federal Trade Commission (“FTC”), the settlement agreement was subject to FTC review and approval. The FTC refused to approve the settlement, inter alia, on the ground that the agreement was anti-competitive because Bristol-Myers had agreed not to market a generic version of Plavix during Apotex’s exclusive license period.

The complaint alleges that in May, 2006, Bodnar, “on behalf of Bristol-Myers and with the knowledge and approval of the Board,” met with Apotex to renegotiate the settlement agreement and that, during the course of that meeting, Bodnar, “at the direction of and with the knowledge and approval of the Board” made an oral representation to Apotex that if the parties reached a revised agreement, Bristol-Myers would not launch a generic version of Plavix. (Complaint, para. 31, 32) On May 25, 2006, “with the knowledge and approval of the Board,” Apotex and Bristol-Myers formally executed a revised settlement agreement that was then submitted to the FTC for review. The revised agreement did not disclose that Bodnar, on behalf of Bristol-Myers, orally represented to Apotex that Bristol-Myers would not launch a generic version of Plavix. However, Apotex, in a letter submission to the FTC, did disclose Bodnar’s oral representation. When the FTC received the Apotex letter, it requested that Bristol-Myers submit a certification that Bristol-Myers, “ha[d] not made any representation, commitment or promise to Apotex, whether oral or written, that is not explicitly set forth in the Revised [] Agreement, including the representation that [Bristol-Myers] would not launch an authorized generic version of Plavix during Apotex’s period of exclusivity.” (Complaint, para. 37). The complaint claims that the Board received and reviewed the FTC’s request, and that, in June, 2006

Bodnar, “at the direction of and with the knowledge and approval of the Board,” signed the certification and submitted it to the FTC. (*Id.*) In June, 2006, Bristol-Myers disclosed that state attorneys general had raised concerns regarding the terms of the revised settlement and on July 27, 2006 Bristol-Myers learned that the Antitrust Division of the Department of Justice was conducting a criminal investigation regarding the proposed settlement of the Plavix litigation. (Complaint, para. 40) On July 28, 2006, Bristol-Myers was notified that the revised settlement had not received clearance from the state attorneys general. (Complaint, para. 42)

On September 12, 2006, Bristol-Myers announced that both CEO Dolan and the company’s general counsel would be leaving their positions immediately. The public announcement explained that it had “received reports from the company’s outside counsel on issues relating to the Plavix patent litigation that were “prepared and delivered at the request of the Board as part of its ongoing assessment of this matter.” (Complaint, para 46) The announcement further explained that during its deliberations, the Board also heard from a former Federal Judge, who had conducted his own inquiry, and recommended that Dolan and the general counsel be terminated. (*Id.*)

Following the denial of regulatory approval of the settlement agreement, Apotex launched its generic product. Bristol-Myers obtained a preliminary injunction that prohibited Apotex from selling the generic drug and, at a subsequent trial, Bristol-Myers prevailed on its patent infringement claim.

In May, 2007, Bristol-Myers announced that it had reached an agreement with the Antitrust Division to resolve the criminal charges by pleading guilty to two counts relating to false statements to a government agency and paying a one million dollar fine.

The complaint claims that throughout the period that the settlement agreement and the company were under scrutiny by the state attorneys general and the Antitrust Division, the price of Bristol Myers's shares declined significantly. As a result, the complaint demands damages in favor of the company for the amount of damages sustained by Bristol-Myers as a result of defendants' alleged misconduct.

In the complaint, plaintiff states that he has not made a pre-litigation demand on the board because the demand would be a futile and useless act in that: (1) the Board is incapable of making an independent and disinterested decision to institute and vigorously prosecute this action and (2) because their actions were illegal and could not have been an exercise of good faith business judgment.

Discussion:

The demand requirements for a derivative suit are determined by the law of the state in which the company is incorporated. Because Bristol-Myers is a Delaware corporation, Delaware law applies. (*See e.g., Hart v. General Motors Corp.*, 129 A.D.2d 179, 183 [1st Dept. 1987] citing *Diamond v. Oreamuno*, 24 N.Y.2d 494, 503 [1969])

The moving defendants contend that under the test articulated in *Rales v. Blasband*, 634 A.2d 927, 934 [Del. 1993], *abrogated on other grounds by Brehm v. Eisner*, 746 A.2d 244 (Del. 2000) (discussed *infra*), the complaint must be dismissed because, plaintiff has failed to plead particularized allegations creating a reasonable doubt that a majority of the directors could respond to a demand with independence and disinterest. Moreover, the moving defendants claim that even if the court finds that the test articulated in *Aronson v. Lewis*, 473 A.2d 805, 814 (Del. 1984) (discussed *infra*) applies to this action, the plaintiff has failed to plead sufficient

particularized allegations to create a reasonable doubt that the directors actions were a good faith exercise of their business judgment.

In opposition, plaintiff contends that the pre-litigation demand on the Board is excused because the well pleaded facts in the complaint create a reasonable doubt that the directors are independent and disinterested and/or that the challenged transaction was otherwise the product of a valid exercise of business judgment.

The issue to be considered on this motion is whether the allegations of the complaint support plaintiff's assertion that a pre-suit demand on the Board would be futile. Under Delaware Chancery Court Rule 23.1, a plaintiff in a derivative suit must seek remedial action from the corporation's Board of Directors. (*Levine v. Smith*, 591 A.2d 194, 200 [Del 1991]) The Delaware "requirement of a demand upon the directors of a corporation to pursue a derivative complaint is a recognition of the inherent powers of the board to manage the affairs of the corporation, which includes making decisions about whether or not to pursue litigation. (*Wilson v. Tully*, 243 A.D.2d 229, 232 [1st Dept 1998]) Because shareholder plaintiffs "must overcome the powerful presumptions of the business judgment rule before they will be permitted to pursue a derivative claim", Delaware law requires that the shareholder plaintiff either make a demand on the Board or plead particularized factual allegations that the demand would be futile. (*Simon v. Becherer*, 7 A.D.3d 66, 71-72 [1st Dept 2004]) Courts have repeatedly emphasized that "conclusory allegations are not considered as expressly pleaded facts or factual inferences." (*Brehm v. Eisner*, 746 A.2d at 255; *David Shaev Profit Sharing Account v. Cayne*, 24 A.D.3d 154 [1st Dept 2005])["conclusory allegations, unsupported by allegations of specific fact" cannot satisfy demand futility requirements]; *Wilson v. Tully*, 243 A.D.2d at 234 ["While the court will

accept well-pleaded facts as true, it will not take as true conclusory allegations of fact or law not supported by allegations of specific fact”)]

Delaware courts have articulated two standards for determining when the demand may be excused as futile. In the first instance, where the Board’s actions are at issue, demand will not be excused unless plaintiff alleges, with particularity, facts creating a reasonable doubt that (1) the directors are disinterested or independent or (2) that the transaction at issue resulted from a valid exercise of business judgment. (*Aronson v. Lewis*, 473 A.2d 805, 814 [Del. 1984]) On the other hand, where the wrong alleged is the Board’s inaction or failure to monitor or supervise, a court need only determine whether the complaint meets the first prong of the *Aronson* test regarding independence and disinterestedness. (*Rales v. Blasband*, 634 A.2d at 934). Here, the *Aronson* test applies because plaintiff challenges the Board’s alleged decisions to approve the settlement agreements; the Board’s alleged direction to Bodnar to make the oral representation to Apotex and its alleged approval of the certification to the FTC that stated that Bristol Myers had not made any oral representations to Apotex.

A. Disinterest and Independence

Under Delaware law,

A director is interested if he will be materially affected, either to his benefit or detriment, by a decision of the board, in a manner not shared by the corporation and the stockholders. The ‘mere threat’ of personal liability in the derivative action does not render a director interested; however, a ‘substantial likelihood’ of personal liability prevents a director from impartially considering a demand.

(*Seminaris Landa*, 662 A.2d 1350, 1354 [Del. Ch. 1995][citing *Rales v. Blasbandi*, 634 A.2d at 936]; *Grimes v. Donald*, 673 A. 2d 1207, 1216 n. 8 [Del 1996][demand on the Board is not deemed futile merely because the directors are named as defendants])

In this case, plaintiff claims that the moving defendants are incapable of independently and disinterestedly considering the demand, because, as members of the Board during the relevant period, they were knowing participants in a criminal conspiracy that resulted in the company's guilty plea and criminal fine. (Complaint, para 60)

However, plaintiff has failed to offer particularized facts to support this conclusion. Instead, plaintiff relies on conclusory allegations that Dolan engaged in misconduct "at the direction of and with the knowledge and approval of the Board." These allegations are insufficient to excuse a demand on the ground of disinterestedness and independence. (*Simon v. Becherer*, 7 S.D.3d at 71-73; *see also, Ratner v. Bidzos*, 2003 Del. Ch. LEXIS 103 at *34 & n.53 (Del. Ch. Sept. 30, 2003) [rejecting demand futility claim where complaint contained only conclusory allegations that the directors knew of and participated in the misconduct]; *In re Forest Laboratories, Inc. Derivative Lit.*, 450 F. Supp. 2d 379 [S.D.N.Y. 2006] [rejecting demand futility claim where the complaint contained only conclusory statements that directors authorized and permitted the wrongdoing])

In *Wilson v. Tully*, 243 A.D.2d at 235, the plaintiff alleged that the Merrill Lynch directors were aware of a history of inappropriate investments but, because municipal financing activities were an important part of the company's business, the directors "made a conscious decision to authorize or permit" allegedly unlawful securities sales to Orange County, CUSTOMER AGREEMENT. There, the court held that demand futility was not established

because plaintiff's conclusory allegations were not supported by particularized facts and that plaintiff failed to "point to any specific conduct of the individual directors" to support the assertions. Accordingly, the court in *Wilson* dismissed the derivative complaint.

Similarly, in *Simon v. Bechereri*, 7 A.D.3d at 68-71, plaintiff complained that J.P. Morgan/Chase directors, by virtue of their oversight roles as members of the risk oversight and audit committees, breached their fiduciary duties by "acquiescing in, approving and/or directing decisions" to have the company participate in allegedly fraudulent transactions with Enron. In that case the court concluded that, in the absence of specific facts demonstrating that the Board members profited from the challenged transactions or personally approved any misconduct, the complaint "fail[ed] to allege, in requisite detail, the substantial likelihood of the directors' liability, and therefore was dismissed.

Moreover, it is settled law that in the context of "futility of demand" in a derivative action, the court will not accept as true the conclusory allegations in the complaint that are not supported by allegations of specific facts. (See, *Wilson v. Tully*, 243 A.D.3d at 234; *David Shaev Profit Sharing Account v. Cayne*, 24 A.D.3d at 154.)

Thus, the complaint fails to satisfy the first prong of the *Aronson* test as it does not allege, with particularity, facts that create a reasonable doubt that the moving directors were disinterested or independent.⁵

⁵ If the first prong of the *Aronson* test is not satisfied, the court may consider whether demand is excused because there is reasonable doubt that the complained of action was the product of valid business judgment. (*Aronson v. Lewis*, 473 A.2d at 814)

B. Business Judgment

The second prong of the *Aronson* analysis “focuses on the substantive nature of the challenged transaction and the Board’s approval thereof.” (*Pogostin v. Rice*, 480 A.2d 619, 624 [Del. 1984].) For the demand to be excused:

Plaintiffs must allege particularized facts that raise doubt about whether the challenged transaction is entitled to the protection of the business judgment rule. Plaintiffs may rebut the presumption that the board’s decision is entitled to deference by raising a reason to doubt whether the board’s action was taken on an informed basis or whether the directors honestly and in good faith believed that the action was in the best interest of the corporation. Thus, plaintiffs must plead particularized facts sufficient to raise (1) a reason to doubt that the action was taken honestly and in good faith or (2) a reason to doubt that the board was adequately informed in making the decision.

Here, again, plaintiff has failed to allege sufficient particularized facts to support the allegations that the actions that were the subject of the Anti Trust Division’s investigation were undertaken with the specific knowledge and consent of the Director Defendants, the movants herein. (Complaint para 61) Simply repeating the mantra that the actions were “at the direction of and with the knowledge and approval of the Board” is not sufficient. Some details should be pleaded, i.e. was their approval at a board meeting? Were all the movants present? Do the minutes contain a accurate report of the discussions relating to this matter? Who made the presentation to the Board, on which the Board wrongfully approved the illegal action, etc. Moreover, he has failed to plead specific facts demonstrating that a majority of the directors were involved in the decision to approve the unlawful conduct. (*See, Wilson v. Tully*, 243 A.D.2d at 229 [demand not futile despite conclusory allegation that directors permitted an illegal course of conduct absent particularized allegations of specific conduct by the directors]; *Andreae v Andreae*, 1992 WL 43924 at *4 [Del. Ch. March 5, 1992][dismissing complaint based on conclusory allegation that the Board approved illegal conduct.

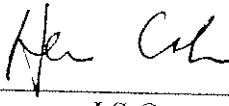
Accordingly, plaintiff has not established the futility of the demand as required by Delaware Chancery Court Rule 23.1.

The Court notes that the dismissal of the complaint is only as to the director defendants. It is not dismissed as to defendants Dolan and Bodnar, although an additional amended complaint should be served.

ORDERED that the motion is granted.

This decision constitutes the order of the court.

DATE: December 11, 2007



J.S.C.

EXHIBIT B



BRISTOL MYERS SQUIBB CO (BMY)

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10-Q

FOR THE QUARTERLY PERIOD ENDING JUNE 30, 2006
Filed on 08/08/2006 – Period: 06/30/2006
File Number 001-01136



[Table of Contents](#)**Note 17. Legal Proceedings and Contingencies (Continued)****INTELLECTUAL PROPERTY****PLAVIX* Litigation**

PLAVIX* is currently the Company's largest product ranked by net sales. Net sales of PLAVIX* were approximately \$3.8 billion for the year ended December 31, 2005. The PLAVIX* patents are subject to a number of challenges in the United States and other less significant markets for the product. It is not possible reasonably to estimate the impact of these lawsuits on the Company. However, loss of market exclusivity of PLAVIX* and development of generic competition would be material to the Company's sales of PLAVIX* and results of operations and cash flows, and could be material to the Company's financial condition and liquidity. The Company currently anticipates that generic clopidogrel bisulfate product will be delivered to customers shortly by Apotex Inc. and Apotex Corp. (Apotex). The Company and Sanofi intend to vigorously pursue enforcement of their patent rights in PLAVIX*.

United States

On March 21, 2006, the Company and Sanofi (the companies) announced that they had executed a proposed settlement agreement (the March Agreement) with Apotex to settle the patent infringement lawsuit pending between the parties in the U.S. District Court for the Southern District of New York. The lawsuit relates to the validity of a composition of a matter patent for clopidogrel bisulfate (the '265 Patent), a medicine made available in the United States by the companies as PLAVIX*. A copy of the March Agreement is filed as an exhibit to this Form 10-Q. The proposed settlement was subject, among other things, to antitrust review and clearance by both the Federal Trade Commission (FTC) and state attorneys general. On June 25, 2006, the companies announced that the March Agreement had been modified by the parties in response to concerns raised by the FTC and the state attorneys general. Both agreements require the parties to cooperate and use all reasonable efforts to facilitate the review by the FTC and the state attorneys general. When the companies announced the proposed settlement, the companies said that there was a significant risk that required antitrust clearance would not be obtained.

The March Agreement included the following provisions, among others: The companies would grant Apotex a royalty-bearing license under the '265 patent to manufacture and sell its FDA-approved generic clopidogrel bisulfate product in the United States, and Apotex would agree not to sell a clopidogrel product in the United States until the effective date of the license. The license would be exclusive for six months (other than for the PLAVIX* brand product) and would be effective September 17, 2011, or earlier in certain specified circumstances. The companies agreed not to launch an authorized generic product during the period in which the Apotex license was exclusive. If the proposed settlement were to become effective, the March Agreement provided for a reimbursement of up to \$40 million by the companies to Apotex relating to Apotex's existing inventory and for provisions in relation to supply arrangements for its clopidogrel bisulfate product. The companies also agreed to compensate Apotex by prescribed amounts in the event that U.S. sales of PLAVIX* were lower than specified amounts during a period immediately preceding the commencement of the license. In the event that the required antitrust clearance was not obtained, a fee would be payable to Apotex by the companies in an amount which varied based on the date on which it was determined that the required antitrust clearance had not been obtained and Apotex would be eligible to receive a reimbursement payment from the companies for certain short-dated inventories, if any, of Apotex's clopidogrel bisulfate product. Any payments to Apotex would be paid 50% by Sanofi and 50% by the Company. In addition, under the March Agreement, if the settlement efforts were terminated, the litigation would be resumed, and Apotex could launch a generic clopidogrel product five business days after such termination although Apotex would be at risk of an award for damages if Apotex were not to prevail in the pending litigation. If Apotex were to launch at risk prior to final resolution of the pending litigation and the companies ultimately prevailed in the pending litigation, the companies agreed their damages would be limited based on varying percentages of Apotex's net sales of such generic clopidogrel bisulfate product but in any event would not exceed 70% of such net sales. In addition, the companies waived their right to seek treble damages under applicable patent laws if they were to prevail in the pending patent litigation. The companies also agreed not to seek a temporary restraining order or a preliminary injunction against a launch by Apotex of its generic clopidogrel bisulfate product (which could not occur until five business days after failure to obtain antitrust clearance) until either they had first given Apotex five business days prior notice of their intention to do so, or Apotex had initiated a launch. The March Agreement provides that the companies would not be required to comply with any provision of the March Agreement that would violate the companies' existing consent decrees with the FTC and state attorneys general.

In response to concerns expressed by the FTC and state attorneys general, the parties modified the March Agreement. A copy of the modified proposed settlement agreement (the Modified Agreement) is filed as an exhibit to this Form 10-Q. Under the terms of the Modified Agreement, Apotex's license would be effective on June 1, 2011, or earlier in certain circumstances. The companies' agreement not to launch an authorized generic product during the term at the Apotex license was also deleted. The provisions relating to a payment to Apotex in the event U.S. sales of PLAVIX* were lower than specified amounts and to a payment to Apotex in the event the required antitrust clearances were not obtained also were deleted. The limitation on damages in the event Apotex launched at risk and the companies prevailed in the pending litigation was reduced to 40% of Apotex's net sales if the companies had launched an authorized generic clopidogrel bisulfate product and otherwise 50% of Apotex's net sales. In addition, the companies again waived their right to seek treble damages under applicable patent laws if they were to prevail in the pending patent litigation. The companies agreed not to seek a temporary restraining order and agreed they could seek a preliminary injunction only after giving Apotex five business days' notice, which notice could be given only after Apotex had initiated a launch. The Modified Agreement provides that the companies would not be required to comply with any provision of the Modified Agreement that would violate the companies' existing consent decrees with the FTC and state attorneys general.

On July 28, 2006, the companies announced that the amended settlement agreement had failed to receive required antitrust clearance from the state attorneys general. When the companies announced the proposed settlement on March 21, 2006, the companies said that there was a significant risk that required antitrust clearance would not be obtained. The FTC has not advised the companies of its decision. However, as noted above, the settlement requires the approval of both the FTC and the state attorneys general to become effective.

Table of Contents

Based on a provision in the Modified Agreement permitting either party to terminate their obligations to pursue the settlement if both required antitrust clearances were not received by July 31, 2006, Apotex has delivered a notice to the companies to terminate their obligations to pursue the settlement effective as of July 31, 2006.

Apotex announced in January 2006 that it had received final approval of its Abbreviated New Drug Application (aNDA) for clopidogrel bisulfate from the FDA. The companies anticipate that generic clopidogrel bisulfate product will be delivered to customers shortly by Apotex. The companies sought leave from the U.S. District Court for the Southern District of New York to move for provisional relief, including a temporary restraining order. The Court declined to entertain such a motion prior to the expiration of the five business day period described above.

The companies are evaluating their legal and commercial options, as well as possible remedies under the agreement with Apotex. If the companies seek and obtain a preliminary injunction halting Apotex's sale of a generic clopidogrel bisulfate product, the companies might be required to post a bond in favor of Apotex to compensate it for any losses Apotex incurs as a result of the preliminary injunction if Apotex ultimately prevails in the pending litigation. The amount, if any, required to be posted cannot be reasonably estimated, but the amount could be material to the Company. There can be no assurance that such a preliminary injunction ruling will be sought or can be obtained.

As previously disclosed, each of the companies recorded reserves in the amount of \$20 million in the first quarter of this year with respect to the potential payments under the proposed settlement. The impact of Apotex's launch of its generic clopidogrel bisulfate product on the Company cannot be reasonably estimated at this time and will depend on a number of factors, including, among others, the amount of generic product sold by Apotex and the pricing of Apotex's generic product; whether the companies seek a preliminary injunction restraining Apotex's sale of its generic product; the amount of time it would take for the Court to consider and act on such a request if made; whether the Court would grant such a request if made; whether, even if a preliminary injunction were obtained, the launch by Apotex would permanently adversely impact the pricing for PLAVIX* and, if so, to what extent; whether the companies launch an authorized generic clopidogrel bisulfate product; when the pending lawsuit is finally resolved and whether the companies prevail; and, even if the parties ultimately prevail in the pending lawsuit, the amount of damages that the parties would be granted and Apotex's ability to pay such damages. Under any circumstances, sustained generic competition for PLAVIX* would be material to the Company's sales of PLAVIX* and results of operations and cash flows, and could be material to the Company's financial condition and liquidity. The Company is evaluating other actions that it may take in order to mitigate the impact of generic competition for PLAVIX*. These actions will vary depending on the extent and duration of such generic competition.

The originally scheduled trial date for the litigation between the companies and Apotex had been suspended pending possible finalization of the proposed settlement. A new trial date has not yet been set by the Court.

As previously disclosed, the Company learned recently that the Antitrust Division of the United States Department of Justice is conducting a criminal investigation regarding the proposed settlement. The Company received a grand jury subpoena to produce documents, the Company's chief executive officer and another senior officer received grand jury subpoenas to provide testimony, and a search warrant was executed at their New York offices. The Company intends to cooperate fully with the investigation. It is not possible at this time reasonably to assess the outcome of the investigation or its impact on the Company.

As previously disclosed, the Company entered into a Deferred Prosecution Agreement (DPA) with the U.S. Attorney's Office for the District of New Jersey (USAO) on June 15, 2005. Pursuant to the DPA, the USAO filed a criminal complaint against the Company alleging conspiracy to commit securities fraud, but deferred prosecution of the Company and will dismiss the complaint after two years if the Company satisfies all the requirements of the DPA. Under the terms of the DPA, the USAO, in its discretion, may prosecute the Company for the matters that were the subject of the criminal complaint filed by the USAO against the Company in connection with the DPA should the USAO make a determination that the Company committed any criminal conduct. Under the DPA, "criminal conduct" is defined as any crime related to the Company's business activities committed by one or more executive officers or director; securities fraud, accounting fraud, financial fraud or other business fraud materially affecting the books and records of publicly filed reports of the Company; and obstruction of justice. It is not possible at this time reasonably to assess the impact, if any, of the pending criminal investigation by the Department of Justice may have on the Company's compliance with the DPA. Additional information with respect to the DPA is included in "Management's Discussion and Analysis—SEC Consent Order and Deferred Prosecution Agreement".

The Company's U.S. territory partnership under its alliance with Sanofi is also a plaintiff in three additional pending patent infringement lawsuits instituted in the U.S. District Court for the Southern District of New York against Dr. Reddy's Laboratories, LTD and Dr. Reddy's Laboratories, Inc. (Dr. Reddy's), Teva Pharmaceuticals USA, Inc. (Teva) and Cobalt Pharmaceuticals Inc. (Cobalt), all related to the '265 patent. The litigation against Dr. Reddy's has been inactive due to the proposed Apotex settlement. A new trial date has not yet been set. The patent infringement actions against Teva and Cobalt have been stayed pending resolution of the Apotex litigation, and the parties to those actions have agreed to be bound by the outcome of the litigation in the District Court against Apotex.

[Table of Contents](#)

The Company's U.S. territory partnership under its alliance with Sanofi is also a plaintiff in another pending patent infringement lawsuit instituted in the U.S. District Court of the District of New Jersey against Watson Pharmaceuticals, Inc. and Watson Laboratories, Inc., based on a different patent related to PLAVIX*. This case has also been stayed pending the outcome of the litigation in the District Court against Apotex.

The Company and Sanofi intend to vigorously pursue enforcement of their patent rights in PLAVIX*.

In related matters, since the announcement of the settlement agreement with Apotex in March 2006, fourteen lawsuits, making essentially the same allegations, have been filed against the Company, Sanofi and Apotex in U.S. District Court, Southern District of Ohio, Western Division, by various plaintiffs, including pharmacy chains (individually and as assignees, in whole or in part, of certain wholesalers), various health and welfare benefit plans/funds and individual residents of various states. These lawsuits allege, among other things, that the Apotex settlement violates the Sherman Act and related laws. The plaintiffs are seeking, among other things,

[Table of Contents](#)**Note 17. Legal Proceedings and Contingencies (Continued)**

permanent injunctive relief barring the Apotex settlement and/or monetary damages. The fourteen lawsuits are comprised of both individual actions and purported class actions. In the cases filed as purported class actions, the plaintiffs are seeking class action status on behalf of similarly situated purchasers. The class actions filed on behalf of direct purchasers have been or are expected to be consolidated under the caption *In re: Plavix Direct Purchaser Antitrust Litigation*, and the class actions filed on behalf of indirect purchasers have been or are expected to be consolidated under the caption *In re: Plavix Indirect Purchaser Antitrust Litigation*. It is not possible at this time reasonably to estimate the impact of these lawsuits on the Company.

International

As previously reported, in March 2005, the Canadian Federal Court of Ottawa rejected Apotex's challenge to the Canadian PLAVIX* patent. The Court also granted Sanofi's application for an order of prohibition against the Minister of Health and Apotex Inc., which would preclude approval of Apotex's Abbreviated New Drug Submission (ANDS) until the patent expires in 2012, unless the Court's decision is reversed on appeal. Apotex's appeal has now been scheduled to be heard in December 2006.

In Korea, in response to separate invalidation actions brought by several generic manufacturers, in June of this year the Korean Intellectual Property Tribunal (IPT) invalidated all claims of Sanofi's Korean Patent 103,094, including claims directed to clopidogrel and pharmaceutically acceptable salts and to clopidogrel bisulfate. Sanofi has filed an appeal with the Patent Court in Korea. It is not possible at this time to reasonably assess the impact of these matters on the Company.

OTHER INTELLECTUAL PROPERTY LITIGATION

ERBITUX* As previously reported, in October 2003, Yeda Research and Development Company Ltd. (Yeda) filed suit against ImClone and Aventis Pharmaceuticals, Inc. in federal court claiming that three individuals associated with Yeda should be named as inventors of U.S. Patent No. 6,217,866, which covers the therapeutic combination of any EGFR – specific monoclonal antibody and anti-neoplastic agents, such as chemotherapeutic agents, for use in treatment of cancer. If Yeda's action were successful, Yeda could be in a position to practice, or to license others to practice, the invention. This could result in product competition for ERBITUX* that might not otherwise occur. Trial on the matter was completed in June 2006, and the parties await a judgment of the court. The Company, which is not a party to this action, is unable to predict the outcome of these proceedings.

As also previously reported, in 2004, Repligen Corporation (Repligen) and Massachusetts Institute of Technology (MIT) filed a lawsuit in the United States District Court for the District of Massachusetts against ImClone, claiming that ImClone's manufacture and sale of ERBITUX* infringes a patent that generally covers a process for protein production in mammalian cells. On July 28, 2006, the Court granted summary judgment in favor of Repligen and MIT by rejecting ImClone's defense of patent exhaustion. The Company is not a party to this action.

ABILIFY* As previously reported, in August 2004, Otsuka filed with the United States Patent and Trademark Office (the USPTO) a Request for Reexamination of the U.S. composition of matter patent covering ABILIFY* (U.S. Patent No. 5,006,528, the '582 Patent). In June 2006, the USPTO officially issued an Ex Parte Reexamination Certificate for the '528 Patent, in which the USPTO confirmed the patentability of all original claims and three new claims.

Securities Litigation**VANLEV Litigation**

As previously reported, the Company and certain of its current and former officers were named as defendants in a number of federal class actions alleging violations of federal securities laws and regulations based on alleged materially misleading statements or failure to disclose material information concerning VANLEV, a drug formerly in development by the Company. In February 2006, the U.S. District Court for the District of New Jersey granted preliminary approval of a settlement between the parties under which the Company paid \$185 million into a settlement fund and agreed to certain non-monetary terms. The \$185 million was fully reserved by the Company in the fourth quarter of 2005. In May 2006, the Court conducted a fairness hearing with respect to the settlement agreement, and subsequently entered final approval of the settlement, awarded attorneys' fees and costs, and approved the plan of allocation. In June 2006, a notice of appeal with respect to the allocation of attorneys' fees and expenses was filed and remains pending.

Other Securities Matters

As previously reported, in September 2005, certain of the Company's current and former officers were named in a purported class action, *Starkman v. Bristol-Myers Squibb et al*, filed in New York State Supreme Court alleging factual claims similar to the now resolved federal class action in the Southern District of New York related to alleged violations of federal securities laws and regulations in connection with sales incentives and wholesaler inventory levels, and asserting common law fraud and breach of

[Table of Contents](#)**PART II—OTHER INFORMATION****Item 1. LEGAL PROCEEDINGS**

Information pertaining to legal proceedings can be found in “Item 1. Financial Statements—Note 17. Legal Proceedings and Contingencies,” to the interim consolidated financial statements, and is incorporated by reference herein.

Item 1A. RISK FACTORS

There have been no material changes in the Company’s risk factors from those disclosed in our 2005 Annual Report on Form 10-K and Form 10-Q for the quarterly period ended March 31, 2006 other than as follows:

*Litigation – PLAVIX**

On March 21, 2006, the Company and Sanofi–Aventis (the companies) announced that they had executed a proposed settlement agreement with Apotex Inc. and Apotex Corp. (Apotex), to settle the patent infringement lawsuit pending between the parties in the U.S. District Court for the Southern District of New York. The lawsuit relates to the validity of a composition of a matter patent for clopidogrel bisulfate (the ‘265 Patent), a medicine made available in the United States by the companies as PLAVIX*. The proposed settlement was subject, among other things, to antitrust review and clearance by both the Federal Trade Commission (FTC) and state attorneys general. On June 25, 2006, the companies announced that the agreement had been modified by the parties in response to concerns raised by the FTC and the state attorneys general. When the companies announced the proposed settlement on March 21, 2006, the companies said that there was a significant risk that the required antitrust clearance would not be obtained.

On July 28, 2006, the companies announced that the amended settlement agreement had failed to receive required antitrust clearance from the state attorneys general. The FTC has not advised the companies of its decision. However, as noted above, the settlement requires the approval of both the FTC and the state attorneys general to become effective.

Based on a provision in the agreement permitting either party to terminate their obligations to pursue the settlement if both required antitrust clearances were not received by July 31, 2006, Apotex has delivered a notice to the companies to terminate their obligations to pursue the settlement effective as of July 31, 2006. Apotex announced in January 2006 that it had received final approval of its Abbreviated New Drug Application (aNDA) for clopidogrel bisulfate from the U.S. Food and Drug Administration. The companies anticipate that generic clopidogrel bisulfate product will be delivered to customers shortly by Apotex. The companies sought leave from the U.S. District Court for the Southern District of New York to move for provisional relief, including a temporary restraining order. The Court declined to entertain such a motion prior to the expiration of the five business day period provided in the settlement agreement. The companies agreed not to seek a temporary restraining order, and they agreed that they could seek a preliminary injunction only after giving Apotex five business days notice, which could be given only after Apotex had initiated a launch.

The companies are evaluating their legal and commercial options as well as possible remedies under the agreement with Apotex. If the companies seek and obtain a preliminary injunction halting Apotex’s sale of a generic clopidogrel bisulfate product, the companies might be required to post a bond in favor of Apotex to compensate it for any losses Apotex incurs as a result of the preliminary injunction if Apotex ultimately prevails in the pending litigation. The amount, if any, required to be posted cannot be reasonably estimated, but the amount could be material to the Company. There can be no assurance that such a preliminary injunction ruling will be sought or can be obtained.

The Company is in the process of assessing the impact of these developments, which are ongoing, and cannot reasonably estimate the impact of such potential generic competition at this time. Under any circumstances, sustained generic competition for PLAVIX* would be material to the Company’s sales of PLAVIX* and results of operations and cash flows, and could be material to the Company’s financial condition and liquidity. The Company is evaluating actions that it may take in order to mitigate the impact of generic competition for PLAVIX*. These actions will vary depending on the extent and duration of such generic competition. Additional information about the pending PLAVIX* patent litigation and the recent adverse developments is included in “Item 1. Financial Statements—Note 17. Legal Proceedings and Contingencies—Intellectual Property—PLAVIX* Litigation” and “Management’s Discussion and Analysis—Outlook.”

The Company learned recently that the Antitrust Division of the United States Department of Justice is conducting a criminal investigation regarding the proposed settlement. The Company intends to cooperate fully with the investigation. It is not possible at this time reasonably to assess the outcome of the investigation or its impact on the Company.

In June 2005, the Company entered into a Deferred Prosecution Agreement (DPA) with the U.S. Attorney’s Office for the District of New Jersey (USAO). Pursuant to the DPA, the USAO filed a criminal complaint against the Company alleging conspiracy to commit securities fraud, but deferred prosecution of the Company and will dismiss the complaint after two years if the Company satisfies all the requirements of the DPA. Under the terms of the DPA, the USAO, in its discretion, may prosecute the Company for the matters that were the subject of the criminal complaint filed by the USAO against the Company in connection with the DPA should the USAO make a determination that the Company committed any criminal conduct. Under the DPA, “criminal conduct” is defined as any crime related to the Company’s business activities committed by one or more executive officers or director; securities fraud, accounting fraud, financial fraud or other business fraud materially affecting the books and records of publicly filed reports of the Company; and obstruction of justice. It is not possible at this time reasonably to assess the impact, if any, the pending criminal investigation by the Department of Justice may have on the Company’s compliance with the DPA. Additional information with respect to the DPA is included in “Management’s Discussion and Analysis—SEC Consent Order and Deferred Prosecution Agreement”.

The Company has recorded significant deferred tax assets related to U.S. foreign tax credit and research tax credit carryforwards which expire in varying amounts beginning in 2012. Realization of foreign tax credit and research tax credit carryforwards is dependent on generating sufficient domestic-sourced taxable income prior to their expiration. Although realization is not assured, assuming the absence of sustained generic competition for PLAVIX*, management believes it is more likely than not that these deferred tax assets will be realized. However, if there is sustained generic competition for PLAVIX* as a result of the outcome of the pending PLAVIX* patent litigation, or otherwise, the Company believes that the amount of foreign tax credit and research tax credit carryforwards considered realizable may be reduced. In such event, the Company may need to record significant additional valuation allowances against these deferred tax assets.

Item 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

The following table summarizes the surrenders of the Company’s equity securities in connection with stock option and restricted stock programs during the six-month period ended June 30, 2006:

Period (Dollars in Millions, Except per Share Data)	Total Number of Shares Purchased ^(a)	Average Price Paid per Share ^(a)	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs ^(b)	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs ^(b)
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EX-99.1

PROPOSED SETTLEMENT AGREEMENT
10-Q Filed on 08/08/2006 - Period: 06/30/2006
File Number 001-01136



Settlement Agreement

Sanofi and Apotex agree to settle the litigations between them involving U.S. Patent No. 4,847,265, 02CV-2255 and 05CV-3965, on the following terms:

1. As used herein, the term "Sanofi" refers to Sanofi-Aventis, Sanofi-Synthelabo, Inc., Bristol-Myers Squibb Company, and the Bristol-Myers Squibb Sanofi Pharmaceuticals Holding Partnership, collectively and individually, and the term "Apotex" refers to Apotex Inc. and Apotex Corp., collectively and individually, and including any entity now or hereafter owned or controlled by any of them.
2. Prior to completion of the Regulatory Review referred to in paragraph 17, the terms of this agreement are and remain confidential and will not be disclosed or used except as required by law or to effectuate the agreement, provided, however, that prior to the end of that review period, Sanofi may disclose the material terms of the agreement in anticipation of, and prior to, an official government request. If Sanofi discloses any of the terms in a manner to make them publicly available, the requirement of confidentiality as to those terms shall expire. If any party wishes to issue a press release, it will first make the text available to all other parties.
3. The pending litigations between Apotex and Sanofi will be terminated by dismissal, without prejudice, of the complaints and all counterclaims, and Apotex releases all claims that it brought or could have brought against Sanofi in connection with these litigations.
4. Apotex is granted a license, under the '265 patent, effective on September 17, 2011 to make, use, import, sell and offer for sale its clopidogrel bisulfate ANDA product in the United States but without the right to grant sub-licenses. However, if Sanofi does not obtain pediatric exclusivity for its clopidogrel bisulfate product by March 1, 2011, then Apotex's license shall become effective on March 17, 2011. If Sanofi obtains a pediatric exclusivity period that is less than 6 months, then Apotex's license shall become effective on a date which is X months earlier than September 17, 2011, where X is calculated as 6 minus the number of months for which Sanofi is granted pediatric exclusivity.
5. The license granted under paragraph 4 shall be exclusive to Apotex, for a period of 6 months except for the reserved right of Sanofi to sell its Plavix brand product, but not to launch an authorized generic.
6. If, through the action of another entity, every basis for Apotex's sole market exclusivity for clopidogrel bisulfate under 21 U.S.C. § 355(j)(5) is triggered before the date specified in paragraph 4, then the license granted to Apotex in paragraph 4 shall commence on that earlier date.
7. Apotex agrees that neither it, nor any lawyers, officers, employees, or fact or expert witnesses who are under Apotex's control will assist, encourage or provide any information to any party in attacking the '265 patent except as compelled by law. If Apotex breaches this provision, any license granted hereunder shall be non-exclusive, Sanofi will have the right to launch an authorized generic at any time, and Apotex shall not be entitled to any of the payments provided in paragraph 15.

8. If an event has occurred that Apotex, in good faith, believes poses a credible threat to constitute a trigger of every basis on which Apotex would have sole exclusivity for clopidogrel bisulfate under the Hatch–Waxman Act, Apotex shall inform Sanofi, giving Sanofi full details thereof. Sanofi shall have 30 days within which to decide whether to accelerate the effective date of Apotex's license. If Sanofi elects not to accelerate the effective date of Apotex's license, and Apotex takes all reasonable steps, as Sanofi directs and at Sanofi's expense, to contest the loss of that exclusivity, and there is a final determination that the event did cause Apotex to lose all or any portion of that exclusivity, Sanofi will compensate Apotex for the economic loss Apotex suffered as a result of the failure to accelerate Apotex's license, the amount of such loss to be determined by arbitration in New York City under the commercial arbitration rules of the American Arbitration Association, using a single arbitrator chosen by the American Arbitration Association who shall have at least 10 years experience, with the arbitrator's fee to be shared equally by Apotex and Sanofi. If possible, the first meeting with the arbitrator shall take place within one month of his/her appointment.
9. During the period that Apotex's license is exclusive, Apotex shall pay to Sanofi a royalty of 1% of its net sales on all sales of its clopidogrel bisulfate product in the United States. Sanofi shall have the right to audit Apotex's sales, using an independent auditor, and at Sanofi's expense.
10. Apotex agrees that it will not sell any clopidogrel product in the United States prior to the date its license under the '265 patent becomes effective. Apotex further agrees that any breach by it of this provision will cause irreparable harm to Sanofi. Apotex hereby irrevocably and unconditionally consents to immediate entry of a temporary restraining order, preliminary injunction and permanent injunction to enforce this provision. Apotex irrevocably and unconditionally consents to personal jurisdiction and venue in the United States District Court for the Southern District of New York for the purpose of enforcing the provisions of this paragraph.
11. Sanofi agrees that, until and during such time as Apotex has an exclusive license under the '265 Patent, it will not launch, or authorize any other party to launch, a generic clopidogrel product in the United States. Sanofi further agrees that any breach by it of this provision will cause irreparable harm to Apotex. Sanofi hereby irrevocably and unconditionally consents to immediate entry of a temporary restraining order, preliminary injunction and permanent injunction to enforce this provision. Sanofi irrevocably and unconditionally consents to personal jurisdiction and venue in the United States District Court for the Southern District of New York for the purpose of enforcing the provisions of this paragraph.
12. The parties understand that Sanofi may be endeavoring to reach an agreement with Dr. Reddy's Laboratories (DRL) that terminates the litigation with that company on the '265 patent. If an agreement with DRL has not been negotiated at the time that Regulatory Clearance, as defined in paragraph 17, has been obtained, then Sanofi at its sole discretion may:
 - 1) terminate this agreement;

2) elect to continue to negotiate with DRL and not terminate this agreement;

Sanofi will inform Apotex when it has concluded an agreement with DRL.

If Sanofi elects to terminate at any time pursuant to this paragraph, or if Sanofi has not concluded an agreement with DRL by June 30, 2006, subject to extensions pursuant to paragraph 18(i), the remaining provisions of this agreement shall apply in the same manner as if Regulatory Clearance was not obtained and Apotex would be entitled to all its rights and remedies available to it as if Regulatory Denial had occurred as of the date Sanofi terminates the agreement, or the ability of Sanofi to obtain extensions under paragraph 18(i) expires.

13. As compensation to Apotex for Apotex's investment in inventory, Sanofi will reimburse Apotex for Apotex's stock of clopidogrel bisulfate bulk and finished goods that are in Apotex's actual possession as of March 31, 2006, for a price not to exceed \$40 million, which Apotex represents and warrants is its actual, fully loaded cost for that inventory, as evidenced by documents Apotex will provide. That sum will be payable within 30 days after Regulatory Clearance (as defined in paragraph 17) with interest from the date of execution of this agreement at an annual interest rate of 6.5%, compounded monthly. Upon execution of this agreement, Apotex will cease writing purchase orders to Signa and will advise Signa not to ship any additional bulk clopidogrel bisulfate until further notice. Apotex will, at Sanofi's election and expense, either deliver to Sanofi, or destroy, all or any portion of that inventory, up to the value of \$40 million.
14. To relieve Apotex from the risk of liability under its agreement with Signa to purchase bulk clopidogrel bisulfate, Sanofi agrees to negotiate in good faith with Signa to obtain a release, for fair value, of any claims that Signa has against Apotex under the Apotex/Signa contract dated June 30, 2000. It is understood, however, that Sanofi is not required by this provision to assume Apotex's obligations or otherwise step into Apotex's shoes under the contract. If a release has not been agreed within 90 days after Regulatory Clearance is obtained, then either Signa or Sanofi may submit the matter to binding arbitration to determine that fair value under the commercial arbitration rules of the American Arbitration Association, using a single arbitrator chosen by AAA, who shall have at least 10 years experience, with the arbitrator's fee to be paid by Sanofi. If possible, the first meeting with the arbitrator shall take place within one month of his/her appointment. If Signa refuses to accept the provisions of this paragraph, then Sanofi agrees to defend Apotex against a suit by Signa with counsel chosen by Sanofi, and (provided Sanofi controls the defense of such suit) to indemnify Apotex against any award or settlement resulting from that suit. Signa will have the right to enforce the provisions of this paragraph. Apotex will not participate in

or advise Signa in connection with the negotiations. However, Apotex may provide any information that it is requested by either Sanofi or Signa, provided Apotex provides that information equally and simultaneously to both Sanofi and Signa. Apotex warrants that neither it nor anyone affiliated with or employed by Apotex will receive directly or indirectly, any financial benefit from any settlement or agreement between Sanofi and Signa. Apotex warrants that the June 30, 2000 contract is the only agreement that Apotex has with Signa or any other supplier that relates to clopidogrel bisulfate except for an agreement dated October 15, 2000 between Brantford Chemicals Inc. and Signa, but Apotex warrants that Apotex will not receive any benefit under that agreement as the result of any negotiation or agreement between Sanofi and Signa pursuant to this paragraph.

15. If Apotex first enters the market pursuant to this agreement as approved by the FTC, Sanofi will compensate Apotex if annualized Plavix U.S. sales, determined by multiplying by four the IMS reported sales for the three months period immediately preceding Apotex's entry, are less than the minimum laid out in the following table:

<u>Year of Apotex's Entry</u>	<u>Annualized Sales Minimum</u>
2007	\$ 3.8B
2008	4.1B
2009	4.3B
2010	4.7B
2011	5B

The amount of the compensation in any year will be one-half of the difference between the above minimum and the annualized IMS sales multiplied by 0.625. Such compensation will be capped at 75% of the compensation that would be due under this formula if IMS sales were \$0.

16. It is expressly understood that no license is granted under any other patent owned or controlled by Sanofi.
17. This agreement is subject to regulatory review by the FTC and state attorneys general ("Regulatory Review"). The parties shall cooperate and use all reasonable efforts to facilitate the review by the FTC and state attorneys general and to respond to requests by such agencies for additional information in a timely manner. The provisions of paragraphs 3–15 of this agreement shall not be or become effective unless and until: (a) the FTC issues an advisory opinion determining that the agreement would not raise issues under Section 5 of the Federal Trade Commission Act, and (b) the state attorneys general provide written notice that they do not object to the agreement (a) and (b) together constituting "Regulatory Clearance". If the FTC, state attorneys general or other governmental agency objects to the agreement, the parties shall use reasonable efforts to continue the Regulatory Review to address such objection and to obtain

Regulatory Clearance, provided that there shall be no material change to the rights and obligations of the parties under this agreement except as they may mutually agree. "Regulatory Denial", as used herein, shall mean any of (i) a denial of approval by either of the FTC or a state attorney general as to which neither party seeks further review or (ii) Sanofi's election to terminate or not to continue (as referred to in paragraph 18(i)) the Regulatory Review or (iii) Sanofi's option to continue Regulatory Review has expired at a time when Regulatory Clearance has not been obtained or (iv) Sanofi has elected to terminate this agreement after continuing negotiations with DRL pursuant to paragraph 12.

18. In the event of Regulatory Denial, the litigations will be resumed as further described in paragraph 19 hereof, and:

- (i) Sanofi will pay Apotex the sum of \$60 million if Regulatory Denial occurs on or before June 30, 2006. If Regulatory Clearance has not been received by June 30, 2006, Sanofi may, at its sole discretion, either terminate the review or, after giving 30 days advance notice to Apotex, permit it to continue month-by-month, by agreeing to pay Apotex the following additional amounts, payable if and when Regulatory Denial occurs:

- To July 31, 2006, \$20 million
- To August 31, 2006, \$20 million
- To September 30, 2006, \$30 million
- To October 31, 2006, \$30 million
- To November 30, 2006, \$40 million
- To December 31, 2006, \$40 million

For avoidance of doubt, by way of example, the notice provision of this paragraph means that Sanofi would be required to give Apotex notice on or before June 1, 2006 in order to extend the Regulatory Review period to July 31, 2006.

In addition, Sanofi will compensate Apotex by reimbursing Apotex for its fully loaded cost for any clopidogrel bisulfate inventory in Apotex's possession that has less than one year of remaining shelf life as of the end of each of those months.

- (ii) Payments defined in sub-paragraph (i) are cumulative and shall be due and payable not later than 30 days after Regulatory Denial. Any amount that is not timely paid by Sanofi shall accrue interest at the rate of 1% per month, compounded monthly.

- (iii) If the litigation results in a judgment that the '265 patent is not invalid or unenforceable, Sanofi agrees that its actual damages for any past infringement by Apotex, up to the date on which Apotex is enjoined, will be 70% of Apotex's net sales of clopidogrel products if Sanofi has not launched an authorized generic and 60% of Apotex's net sales if Sanofi has launched an authorized generic. Sanofi further agrees that it will not seek increased damages under 35 U.S.C. § 284.
19. Sanofi and Apotex will jointly request that the court adjourn the presently set trial date of June 12, 2006 and adjourn all due dates, but retain jurisdiction, in the litigation between Sanofi and Apotex and DRL to permit the Regulatory Review of this agreement. If the Regulatory Review results in Regulatory Denial, Sanofi and Apotex will jointly request that the court reset the June 12, 2006 trial date to a date that is not earlier than 2 1/2 months from the date on which the request is made. Apotex agrees that it will not launch a generic clopidogrel product during the time of the Regulatory Review and Sanofi agrees it will not launch an authorized generic clopidogrel product during the time of the Regulatory Review. The parties agree that they shall jointly seek issuance of a court order embodying the provisions of this paragraph 19. Further, it is agreed that if the Regulatory Review results in Regulatory Denial then,
- (i) Until 5 business days after the date on which Regulatory Denial is effective (not counting the day on which it becomes effective), Apotex will not launch a generic clopidogrel product and Sanofi will not launch an authorized generic product, and Sanofi will not seek a temporary restraining order or a preliminary injunction.
 - (ii) After the expiration of the period defined in sub-paragraph (i), Sanofi agrees that it will not launch an authorized generic clopidogrel product before a launch by Apotex of a generic clopidogrel product, and Sanofi will not file for a temporary restraining order or preliminary injunction until either: (1) Sanofi gives Apotex 5 business days notice (not counting the day on which notice is given) of its intention to do so; or (2) Apotex has initiated a launch of a generic clopidogrel product.
20. No provision of this agreement shall require Sanofi or Apotex to do any act that violates any term of any of the FTC consent decrees or court injunctions to which Sanofi is subject, or is otherwise unlawful.

Signed and agreed on March 17, 2006

For Apotex Inc. and Apotex Corp.

/s/ Barry Sherman

For Sanofi-Aventis

/s/ Jean-Pierre Kerjouan

For Bristol-Myers Squibb Company

/s/ Andrew G. Bodnar

For Bristol-Myers Squibb Sanofi
Pharmaceuticals Holding Partnership

/s/ Andrew G. Bodnar

/s/ Jean-Pierre Kerjouan



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EX-99.2

MODIFIED PROPOSED SETTLEMENT AGREEMENT
10-Q Filed on 08/08/2006 - Period: 06/30/2006
File Number 001-01136



Settlement Agreement

Sanofi and Apotex agree to settle the litigations between them involving U.S. Patent No. 4,847,265, 02CV-2255 and 05CV-3965, on the following terms:

1. As used herein, the term "Sanofi" refers to Sanofi-Aventis, Sanofi-Synthelabo, Inc., Bristol-Myers Squibb Company, and the Bristol-Myers Squibb Sanofi Pharmaceuticals Holding Partnership, collectively and individually, and the term "Apotex" refers to Apotex Inc. and Apotex Corp., collectively and individually, and including any entity now or hereafter owned or controlled by any of them.
2. Prior to completion of the Regulatory Review referred to in paragraph 13, the terms of this agreement are and remain confidential and will not be disclosed or used except as required by law or to effectuate the agreement, provided, however, that prior to the end of that review period, Sanofi may disclose the material terms of the agreement in anticipation of, and prior to, an official government request. If Sanofi discloses any of the terms in a manner to make them publicly available, the requirement of confidentiality as to those terms shall expire. If any party wishes to issue a press release, it will first make the text available to all other parties.
3. The pending litigations between Apotex and Sanofi will be terminated by dismissal, without prejudice, of the complaints and all counterclaims, and Apotex releases all claims that it brought or could have brought against Sanofi in connection with these litigations.
4. Apotex is granted a license, under the '265 patent, effective on June 1, 2011 to make, use, import, sell and offer for sale its clopidogrel bisulfate ANDA product in the United States but without the right to grant sub-licenses and Sanofi will not waive its pediatric exclusivity with respect to any other ANDA filer prior to January 31, 2012. However, if Sanofi does not obtain pediatric exclusivity for its clopidogrel bisulfate product by March 15, 2011, then Apotex's license shall become effective on April 1, 2011.
5. In the event that Sanofi launches a drug product (other than Plavix), an active ingredient of which is an anti-platelet aggregation agent, in the United States, prior to the effective date of Apotex's license under the '265 Patent, then Apotex shall be granted a license to make, use, offer for sale, sell, and import such drug product in the United States, under all patents applicable to that drug product owned by or licensed to Sanofi, effective on the date which is the effective date of Apotex's license under the '265 Patent pursuant to this agreement.
6. If, through the action of another entity, every basis for Apotex's sole market exclusivity for clopidogrel bisulfate under 21 U.S.C. § 355(j)(5) is triggered before the date specified in paragraph 4, then the license granted to Apotex in paragraph 4 shall commence on that earlier date.
7. Apotex agrees that neither it, nor any lawyers, officers, employees, or fact or expert witnesses who are under Apotex's control will assist, encourage or provide any information to any party in attacking the '265 patent except as compelled by law.

8. If an event has occurred that Apotex, in good faith, believes poses a credible threat to constitute a trigger of every basis on which Apotex would have sole exclusivity for clopidogrel bisulfate under the Hatch–Waxman Act, Apotex shall inform Sanofi, giving Sanofi full details thereof. Sanofi shall have 30 days within which to decide whether to accelerate the effective date of Apotex's license. For purposes of this paragraph, "trigger" shall mean forfeiture, cancellation, or loss for any reason. If Sanofi elects not to accelerate the effective date of Apotex's license, and Apotex takes all reasonable steps, as Sanofi directs and at Sanofi's expense, to contest the loss of that exclusivity, and there is a final determination that the event did cause Apotex to lose all or any portion of that exclusivity, Sanofi will compensate Apotex for the economic loss Apotex suffered as a result of the failure to accelerate Apotex's license, the amount of such loss to be determined by arbitration in New York City under the commercial arbitration rules of the American Arbitration Association, using a single arbitrator chosen by the American Arbitration Association who shall have at least 10 years experience, with the arbitrator's fee to be shared equally by Apotex and Sanofi. If possible, the first meeting with the arbitrator shall take place within one month of his/her appointment.
9. Apotex agrees that it will not sell any clopidogrel product in the United States prior to the date its license under the '265 patent becomes effective. Apotex further agrees that any breach by it of this provision will cause irreparable harm to Sanofi. Apotex hereby irrevocably and unconditionally consents to immediate entry of a temporary restraining order, preliminary injunction and permanent injunction to enforce this provision. Apotex irrevocably and unconditionally consents to personal jurisdiction and venue in the United States District Court for the Southern District of New York for the purpose of enforcing the provisions of this paragraph.
10. As compensation to Apotex for Apotex's investment in inventory, Sanofi will reimburse Apotex for Apotex's stock of clopidogrel bisulfate bulk and finished goods that are in Apotex's actual possession as of March 31, 2006, for a price not to exceed \$40 million, which Apotex represents and warrants is its actual, fully loaded cost for that inventory, as evidenced by documents Apotex will provide. That sum will be payable within 30 days after Regulatory Clearance (as defined in paragraph 13) with interest from the date of execution of this agreement at an annual interest rate of 6.5%, compounded monthly. Upon execution of this agreement, Apotex will cease writing purchase orders to Signa and will advise Signa not to ship any additional bulk clopidogrel bisulfate until further notice. Apotex will, at Sanofi's election and expense, either deliver to Sanofi, or destroy, all or any portion of that inventory, up to the value of \$40 million.

11. To relieve Apotex from the risk of liability under its agreement with Signa to purchase bulk clopidogrel bisulfate, Sanofi agrees to negotiate in good faith with Signa to obtain a release, for fair value, of any claims that Signa has against Apotex under the Apotex/Signa contract dated June 30, 2000. It is understood, however, that Sanofi is not required by this provision to assume Apotex's obligations or otherwise step into Apotex's shoes under the contract. If a release has not been agreed within 90 days after Regulatory Clearance is obtained, then either Signa or Sanofi may submit the matter to binding arbitration to determine that fair value under the commercial arbitration rules of the American Arbitration Association, using a single arbitrator chosen by AAA, who shall have at least 10 years experience, with the arbitrator's fee to be paid by Sanofi. If possible, the first meeting with the arbitrator shall take place within one month of his/her appointment. If Signa refuses to accept the provisions of this paragraph, then Sanofi agrees to defend Apotex against a suit by Signa with counsel chosen by Sanofi, and (provided Sanofi controls the defense of such suit) to indemnify Apotex against any award or settlement resulting from that suit. Signa will have the right to enforce the provisions of this paragraph. Apotex will not participate in or advise Signa in connection with the negotiations. However, Apotex may provide any information that is requested by either Sanofi or Signa, provided Apotex provides that information equally and simultaneously to both Sanofi and Signa. Apotex warrants that neither it nor anyone affiliated with or employed by Apotex will receive directly or indirectly, any financial benefit from any settlement or agreement between Sanofi and Signa. Apotex warrants that the June 30, 2000 contract is the only agreement that Apotex has with Signa or any other supplier that relates to clopidogrel bisulfate except for an agreement dated October 15, 2000 between Brantford Chemicals Inc. and Signa, but Apotex warrants that Apotex will not receive any benefit under that agreement as the result of any negotiation or agreement between Sanofi and Signa pursuant to this paragraph.
12. It is expressly understood that, except as provided in paragraph 5 above, no license is granted under any other patent owned or controlled by Sanofi.
13. This agreement is subject to regulatory review by the FTC and state attorneys general ("Regulatory Review"). The parties shall cooperate and use all reasonable efforts to facilitate the review by the FTC and state attorneys general and to respond to requests by such agencies for additional information in a timely manner. The provisions of paragraphs 3–12 of this agreement shall not be or become effective unless and until: (a) the FTC issues an advisory opinion determining that the agreement would not raise issues under Section 5 of the Federal Trade Commission Act, and (b) the state attorneys general provide written notice that they do not object to the agreement, (a) and (b) together constituting "Regulatory Clearance". If the FTC, state attorneys general or other governmental agency objects to the agreement, the parties shall use reasonable efforts to continue the Regulatory Review to address such objection and to obtain Regulatory Clearance, provided that there shall be no material change to the rights and obligations of the parties under this agreement except as they may mutually agree. "Regulatory Denial", as used herein, shall mean a denial of approval by

either of the FTC or a state attorney general as to which neither party seeks further review. If Regulatory Review has not been completed by July 31, 2006, either party has the right to declare that there has been Regulatory Denial.

14. In the event of Regulatory Denial, the litigations will be resumed as further described in paragraph 15 hereof, and:
- (i) Sanofi will compensate Apotex by reimbursing Apotex for its fully loaded cost for any clopidogrel bisulfate inventory in Apotex's possession that has less than one year of remaining shelf life as of the end of each of those months, provided, however, that Apotex shall relabel its inventory to the extent possible to extend its expiration date, and Sanofi shall pay Apotex an amount not to exceed \$500,000 to effectuate that relabelling.
 - (ii) If the litigation results in a judgment that the '265 patent is not invalid or unenforceable, Sanofi agrees that its actual damages for any past infringement by Apotex, up to the date on which Apotex is enjoined, will be 50% of Apotex's net sales of clopidogrel products if Sanofi has not launched an authorized generic and 40% of Apotex's net sales if Sanofi has launched an authorized generic. Sanofi further agrees that it will not seek increased damages under 35 U.S.C. §284.
15. Sanofi and Apotex will jointly request that the court maintain the litigation between them on the court's suspense docket to permit the Regulatory Review of this agreement. If the Regulatory Review results in Regulatory Denial, Sanofi and Apotex will jointly request that the court reset the trial date to a date that is not earlier than 2 ¹/₂ months from the date on which the request is made. Apotex agrees that it will not launch a generic clopidogrel product during the time of the Regulatory Review and Sanofi agrees it will not launch an authorized generic clopidogrel product during the time of the Regulatory Review. The parties agree that they shall jointly seek issuance of a court order embodying the provisions of this paragraph. Further, it is agreed that if the Regulatory Review results in Regulatory Denial then,
- (i) Until 5 business days after the date on which Regulatory Denial is effective (not counting the day on which it becomes effective), Apotex will not launch a generic clopidogrel product and Sanofi will not launch an authorized generic product, and Sanofi will not seek a temporary restraining order or a preliminary injunction.
 - (ii) After the expiration of the period defined in sub-paragraph (i), Sanofi agrees that it will not launch an authorized generic clopidogrel product before a launch by Apotex of a

generic clopidogrel product, and Sanofi will not, at any time, file for a temporary restraining order, and will not file for a preliminary injunction until Sanofi gives Apotex 5 business days notice (not counting the day on which notice is given) of its intention to do so, which notice will not be given before Apotex has initiated a launch of a generic clopidogrel product.

16. No provision of this agreement shall require Sanofi or Apotex to do any act that violates any term of any of the FTC consent decrees or court injunctions to which Sanofi is subject, or is otherwise unlawful
17. This agreement may be executed in counterparts by each of the parties hereto.

Signed and agreed on May 26, 2006

For Apotex Inc. and Apotex Corp.

/s/ Barry Sherman

For Sanofi-Aventis

/s/ Jean-Pierre Kerjouan

For Bristol-Myers Squibb Company

/s/ Andrew G. Bodnar

For Bristol-Myers Squibb Sanofi
Pharmaceuticals Holding Partnership

/s/ Andrew G. Bodnar

/s/ Jean-Pierre Kerjouan